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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/787,079 | 03/07/2001 | Jorg Rosenberg | 0480/001216 | 1470 |
| 26474 | 7590 | 01/17/2006 | EXAMINER | |
| NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 400 EAST WASHINGTON, DC 20005 | | | HUSON, MONICA ANNE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1732 | |

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 09/787,079 | Applicant(s) ROSENBERG ET AL. | |
| | Examiner Monica A. Huson | Art Unit 1732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the Amendment filed 8 December 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dabal et al. (U.S. Patent 4,072,551). Regarding Claim 1, Dabal et al., hereafter “Dabal,” show that it is known to carry out a method for producing tablets by melt extrusion (Column 8, lines 1-44; Column 10, lines 3-13), in which an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip, wherein, in a first stage, the still deformable product strip is compressed to a continuous tablet belt, the individual tablets in the belt being connected together by product webs (Figure 5, element 82, 83), in a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt (Figure 5, printing unit; It is noted that ambient cooling will take place along the transport sections.), in a third stage, downstream of the second stage, the tablets are mechanically singulated in a continuous process (Figure 5, unitizing unit), and then the singulated tablets are transported further to a fourth stage downstream of the said third stage where the singulated tablets are subsequently deflashed (Column 32, lines 13-18).

Regarding Claim 2, Dabal shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein a force with a component perpendicular to the plane of the tablet belt is allowed to act on the tablet belt for singulation of the tablet (Figure 5, unitizing unit; It is noted that the force exerted by the roller will have at least two components.).

Regarding Claim 3, Dabal shows the process as claimed as discussed in the rejection of Claim 2 above, including a method wherein a force with a component parallel to the plane of the tablet belt is allowed to act on the tablet belt for singulation of the tablets (Figure 5, unitizing unit; It is noted that the force exerted by the roller will have at least two components.).

Regarding Claim 5, Dabal shows the process as claimed as discussed in the rejection of Claim 3 above, including a method wherein the parallel force component is generated by exerting a traction force on the solidified tablet belt (Figure 5, unitizing unit; It is noted that the force exerted by the rollers will include some traction force.).

Regarding Claim 12, Dabal shows that it is known to have an apparatus for producing tablets (Figure 5), comprising at least one extruder means for heating a pharmaceutical mixture (Column 8, lines 1-44; Column 10, lines 3-13); means for shaping a tablet belt from said extruded heated pharmaceutical mixture arranged downstream of said extruder (Figure 5, element 82, 83); first transport means for said tablet belt comprising means for cooling the extruded tablet belts and which is arranged downstream of said shaping means (Figure 5, printing unit; It is noted that ambient cooling will take place along the transport sections.), and means for singulating and deflashing said tablets, wherein said means for singulating and deflashing said tablets comprise at least one singulating means arranged downstream of said first

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transport means and at least one deflashing means arranged downstream of said singulating means and spatially separate therefrom (Figure 5, unitizing unit; Column 32, lines 13-18; It is noted that the transport means is the tension force that is generated by the two rollers acting together on the tablet belt.).

Regarding Claim 7, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 12 above, including a machine wherein the singulating means comprises at least one rotatable roller (Figure 5, unitizing unit).

Regarding Claim 8, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 7 above, including a machine wherein the singulating means comprises two counter-rotating rollers which can be pressed against one another (Figure 5, unitizing unit).

Regarding Claim 9, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 12 above, including a machine wherein the singulating means comprises at least one embossed roller (Column 22, lines 58-63).

Regarding Claim 11, Dabal shows the apparatus as claimed as discussed in the rejection of Claim 12 above, including a machine wherein a second transport means is provided between the singulating means and the deflashing means and the deflashing means comprises a shaking or vibrating unit (Column 30, lines 12-19; Column 32, lines 13-18; It is noted that by suggesting that the tablets are amenable to online testing throughout their production, Dabal implies that the tablets are transported from the unitizing to the deflashing operation in a predetermined fashion.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dabal, in view of Klimesch et al. (U.S. Patent 5,073,379). Dabal shows the process as claimed as discussed in the rejection of Claims 1 and 2 above, but he does not show a directional force that diverts the tablet belt in a specific direction. Klimesch '379 shows that it is known to carry out a method wherein the perpendicular force component is generated by diverting the solidified tablet belt out of its transport plane (Figure 1; Column 2, lines 61-67). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's diverting force to tabulate Dabal's belt in order to most efficiently achieve the unitizing operation.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Monica A Huson
January 9, 2006


MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER